K083425

510(k) Summary
Lucent® Magnum+

FEB 13 2009

510(k) Number_____

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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760-607-0121

Contact Information:
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Date Prepared: February 9, 2009

Device Identification	
Proprietary Name	Lucent® Magnum+
Common Name	Intervertebral Body Fusion Device
Device Classification	21CFR 888.3080 (orthosis, spinal intervertebral fusion)
Proposed Regulatory Class	Class II
Device Product Code	MAX

Device Description

Spinal Elements' Lucent Magnum+ device is composed of a main device body (spacer) and fixation screws. The spacer is generally oval-shaped with various holes throughout its geometry. The superior and inferior surfaces of the spacer have engagement members to help prevent migration once surgically positioned. The spacer has holes through it that allow for the passage of bone screws that affix to bone to help prevent migration.

Devices are available in a multitude of sizes. The spacer may be made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3 or polyetheretherketone (PEEK-OPTIMA LTI, provided by Invibio) conforming to ASTM F 2026. Because PEEK is radiolucent, tantalum (per ASTM F 560) pins are embedded into PEEK spacers to serve as markers for radiographic visualization of spacer orientation. Screws are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3. All implants are intended for single use only and should not be reused under any circumstances. Components from this system should not be used in conjunction with components from other systems.

Intended Use of the Device
Magnum+ is a stand alone device intended to be used with bone screws. If the physician chooses to use fewer than the maximum number of screws accommodated by the device, then additional supplemental fixation, which has been cleared by the FDA for use in the lumbar spine, must be used to augment stability.

When used as a vertebral body replacement:
When used as a vertebral body replacement, the device is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

The interior of the spacer can be packed with allograft or autograft.

When used as an intervertebral body fusion device:
Lucent Magnum+ is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

Substantial Equivalence
The Lucent Magnum+ device was shown to be substantially equivalent in indications for use, general design features, function, and materials to the following predicates: Lucent® by Spinal Elements (K071724), STALIF TT™ by Surgicraft (K073109), and Solitaire™ by Biomet Spine (K081395).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Spinal Elements, Incorporated
% Ms. Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K083475
Trade/Device Name: Lucent® Magnum+
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MQP
Dated: November 21, 2008
Received: November 24, 2008

Dear Ms. DiMartino:

This letter corrects our substantially equivalent letter of February 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Lucent® Magnum+

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083475